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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,198	07/29/2003	Yen-Lin Chen	U 014740-4	5680
7590	12/05/2005		EXAMINER	
Ladas & Parry 26 West 61st Street New York, NY 10023			AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 12/05/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/629,198

Applicant(s)

CHEN ET AL.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_.

- 5) ☐ Notice of Informal Patent Application (PTO-152)

- 6) ☒ Other: Translation 4 JP 7-274578; JP 12-275163

### **DETAILED ACTION**

Claims 3-5 as amended (10/14/2005) are under examination.

Claims 1 and 2 are canceled (10/14/2005).

Claims 6-26 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention. Election was made without traverse in the prior reply (4/25/2005). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election was treated as an election without traverse (MPEP § 818.03(a)). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

### ***Response to Arguments***

Applicant's arguments filed 10/14/2005 have been fully considered but they are not all found persuasive for the reasons below.

### ***Claim Rejections - 35 USC § 112***

#### ***Deposit***

Claims 3-5 remain rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as explained in the last office action and for the reasons below.

The ATCC deposits for specific microbial strains *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485) were made under the terms of the Budapest Treaty (specification page 4; ATCC deposit receipts; arguments filed 10/14/2005) that satisfy the viability requirements. However, no declaration stating that all restrictions

Art Unit: 1651

imposed by the depositor on availability to the public of the deposited materials will be irrevocably removed, has been submitted. Thus, the public availability requirement has not been satisfied.

An affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent will overcome this rejection.

### *Indefinite*

Claim 3 as amended is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 as amended is indefinite with regard to those “characteristics” that are identical to the characteristics of deposited strains ATCC PTA-4485 (M1033) and ATCC PTA-4486 (M022). The characteristics as intended are unclear. It is suggested to use language, for example: “which has all of the identifying characteristics identical to those of” ATCC PTA-4485 (M1033) and ATCC PTA-4486 (M022), for characterization of an isolated mutant of the amended claim 3.

### *Double Patenting*

Claim rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US 6,635,467 (Chen et al.) has been withdrawn due to cancellation of claims 1 and 2 in the instant application.

***Claim Rejections - 35 USC § 102***

Claim rejection under 35 U.S.C. 102(e) as being anticipated by US 6,635,467 (Chen et al.) in the light of evidence by JP 2000279163 has been withdrawn due to cancellation of claims 1 and 2.

***Claim Rejections - 35 USC § 102/103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 3 as amended remains rejected under 35 U.S.C. 102(e) as anticipated by US 6,635,467 (Chen et al.) or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,635,467 (Chen et al.) in the light of evidence by JP 2000279163 as explained in the prior office action and for the reasons below.

Claim is directed to a mutant of *Monascus purpureus* that has some characteristics identical to the characteristics of strains *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485).

The claimed invention is indefinite with regard to identical characteristics as intended.

The cited patent US 6,635,467 (Chen et al.) discloses the mutant(s) including parent strain *Monascus purpureus* CCRC 31499 and its derivative mutant M011 that is obtained by mutagenesis as the strains of the instant invention. The microorganisms of the cited US 6,635,467 (Chen et al.) have at least some characteristics identical to the characteristics of the presently claimed *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485) such as capability to grow on rice and soybean powder and magnesium sulfate (col. 3, lines 39-41) and capability to produce non-toxic fermentation

Art Unit: 1651

products due to low amounts of citrinin. Consequently, the claimed strains appear to be anticipated by the patent as was explained in the prior office action.

In the alternative, even if the claimed microorganisms are not identical to the referenced microorganisms with regard to some unidentified characteristics including GABA production, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely to inherently possess the same characteristics of the claimed microorganisms particularly in view of the similar characteristics which they have been shown to share. Moreover, the GABA product is a *Monascus* fermentation product on rice and soybean powders in the light of evidence by JP 2000279163 (English abstract). Thus, the strain of the amended claim 3 would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 3 as amended remains rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000279163 and JP 7274978 as explained in the prior office action and for the reasons below.

Claim is directed to a mutant of *Monascus purpureus* that has some characteristics identical to the characteristics of strains *Monascus purpureus* M022 (ATCC PTA 4486) and *Monascus purpureus* M01033 (ATCC PTA 4485).

JP 7274978 teaches that microbial cultures and/or strains belonging to *Monascus* including *Monascus purpureus* are capable to produce non-toxic edible fermentation product(s) due to low amounts of citrinin (English abstract).

JP 2000279163 teaches that that microbial cultures and/or strains belonging to *Monascus* are capable to grow on rice and soybean powders and to produce edible and therapeutic fermentation product(s) including GABA products (English abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain *Monascus* cultures including *Monascus purpureus* producing non-toxic fermentation product(s) with GABA due to low amounts of citrinin with a reasonable expectation of success because the prior art demonstrates that *Monascus* cultures including *Monascus purpureus* are known to produce GABA and to have low amounts of toxic citrinin. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. One of skill in the art would have been motivated to select cultures producing GABA and having low contents of citrinin for the expected benefits in obtaining edible and therapeutic fermentation products of *Monascus* cultures.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Rejection of claims 4 and 5 under 35 U.S.C. 102(e) as anticipated by US 6,635,467 (Chen et al.) or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 6,635,467 (Chen et al.) in the light of evidence by JP 2000279163 and under 35 U.S.C. 103(a) as being unpatentable over JP 2000279163 and JP 7274978 have been withdrawn in the light of the Applicant's Declaration

Art Unit: 1651

filed 10/14/2005 that demonstrates morphological and functional differences between the cited prior art strains and the presently claimed strains ATCC PTA 4486 and ATCC PTA 4485. See also response filed 10/14/2005, pages 7-8. Thus, the prior art neither teaches nor fairly suggests the presently claimed strains ATCC PTA 4486 and ATCC PTA 4485.

Claims 4 and 5 are free of prior art and might be allowed upon resolution of 112-1 issues as explained above and when presented in independent form in the lack of resolution of 112-2 issues.

No claims are allowed in the instant office action.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

November 29, 2005

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER